

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

**IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

Honorable Karen M. Williams,  
Magistrate Judge

Honorable Thomas Vanaskie  
(Ret.), Special Discovery  
Master

**MOTION TO PARTIALLY STRIKE REPLY BRIEF IN SUPPORT OF  
PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF DOCUMENTS  
WITHHELD AS CHINESE STATE SECRETS, OR FOR LEAVE TO FILE  
A SUR-REPLY**

Zhejiang Huahai Pharmaceutical Co., Ltd, Huahai US, Inc., Princeton Pharmaceutical Inc., and Solco Healthcare U.S., LLC (collectively the “ZHP Parties”), respectfully move this Court for an Order striking certain arguments in Plaintiffs’ reply brief in support of their Motion to Compel Production of Documents Withheld as Chinese State Secrets (*see* [Dkt. 1273](#)) because Plaintiffs’ reply brief raises, *for the first time*, arguments with respect to *Societe Nationale Industrielle Aerospatiale v. United States Dist. Ct.*, S.D. Iowa, 482 U.S. 522 (1987) and *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468 (9th Cir. 1992). Alternatively, the ZHP Parties request the Court grant the ZHP Parties leave to file

a sur-reply to address Plaintiffs' new arguments, and request the Court deem this brief the ZHP Parties' sur-reply.

As Plaintiffs failed to make their new arguments in their opening brief, those arguments must be stricken from the record and disregarded by this Court, or the ZHP Parties should be afforded the opportunity to respond to Plaintiffs' new arguments, as set forth herein.

## **I. LEGAL STANDARD**

“It is axiomatic that reply briefs should respond to the respondent’s arguments or explain a position in the initial brief that the respondent has refuted.” *Bayer AG v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705, 716 (D.N.J. 2001), *aff’d sub nom. Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306 (Fed. Cir. 2002). “The rationale for this rule is self-evident-because the local rules do not permit sur-reply briefs, *see* L.Civ.R. 7.1(d),” and so the opposing party “has no opportunity to respond to newly minted arguments contained in reply briefs.” *Id.* “Furthermore, a ‘passing reference’ to an issue in an opening brief will not suffice to put a party on notice that the moving party is moving on that particular issue.” *Id.* Thus, the appropriate remedy for the presentation of arguments made for the first time in a reply brief is that such arguments be stricken from the record and disregarded by the Court in deciding the motion. *Id.*

## II. ARGUMENT

### A. Plaintiffs failed to make more than a “passing reference” to the *Aerospatiale* and *Richmark* factors in their opening brief, and all arguments in Plaintiffs’ reply brief based on such factors should therefore be stricken.

Despite the fact that this Court has expressly stated that it is “going to apply the *Aerospatiale* and *Richmark* factors” to decide issues related to documents withheld from production on the basis of China’s state secrecy laws (*see* 3-16-21 Hrg. Tr. at 27:11-13), Plaintiffs’ opening brief failed to address these factors in any meaningful way. Although Plaintiffs listed the *Aerospatiale* factors in their Memorandum of Law, they failed to analyze a single factor as it relates to the documents at issue. *See* [Dkt. 1231](#) at 15-16. Instead, Plaintiffs argued that because the ZHP Parties have not made a showing of the “present danger” of the consequences of production, the documents must be produced. *See* [Dkt. 1231](#) at 16-17. However, as set forth in the ZHP Parties’ brief in opposition to the motion to compel, the “present danger” test proposed by Plaintiffs has no basis in law, and each of the factors set forth in *Aerospatiale* and *Richmark* weigh in favor of the ZHP Parties. *See* Opposition Br., [Dkt. 1267](#) at 6-8.

Having failed in their opening brief to present more than a “passing reference” to the operative legal standard for deciding the motion to compel, Plaintiffs now seek, for the first time, to present argument on certain of the *Aerospatiale* and *Richmark* factors, devoting nearly six pages of new argument to these factors in their

reply brief. *See Dkt. 1273* at 8-13. However, having made the decision to rely on a manufactured “present danger” standard in their motion and opening brief—presumably because the *Aerospatiale* and *Richmark* factors overwhelmingly weigh in favor of the ZHP Parties—Plaintiffs should not be rewarded for their attempt to obfuscate the correct legal standard by being permitted to present new legal arguments in their reply brief. Accordingly, all arguments related to the *Aerospatiale* and *Richmark* factors set forth in Plaintiffs’ reply brief should be stricken from the record.

**B. Even if Plaintiffs’ new arguments are considered by the Court, the *Aerospatiale* and *Richmark* factors overwhelmingly weigh in favor of the ZHP Parties.**

As noted by the court in *Bayer*, the rationale for the rule barring a movant from presenting new arguments in a reply brief “is self-evident-because the local rules do not permit sur-reply briefs, *see* L.Civ.R. 7.1(d),” and so the opposing party “has no opportunity to respond to newly minted arguments contained in reply briefs.” *Bayer AG*, 129 F. Supp. 2d at 716. Here, although the ZHP Parties have not had any opportunity to fully respond to Plaintiffs’ arguments related to the *Aerospatiale* and *Richmark* factors, it is evident those factors still weigh in favor of the ZHP Parties:

- Plaintiffs have not, and cannot, present any argument as to why ZHP’s communications with Chinese regulatory authorities are *vital* to the issues related to the ZHP Parties’ potential liability as required by the first *Aerospatiale* factor. Rather, the standard described by Plaintiffs in their reply

brief, and which they urge the Court to apply, is tantamount to mere responsiveness to a document request. Indeed, the document on which Plaintiffs rely (*see Dkt. 1273* at 9), while responsive to Plaintiffs' document requests, is not vital to Plaintiffs' claims and, moreover, is the type of internal technical investigation and report *that has already been produced to Plaintiffs and is not the subject of the motion*.

- Despite Plaintiffs' argument otherwise, the fact that the document requests at issue are "court ordered" (*see Dkt. 1273* at 10) has absolutely no bearing on the *Aerospatiale* and *Richmark* factors. Rather, the second *Aerospatiale* factor requires the Court to consider the degree of specificity of the requests. Here, it is uncontested that Defendants requested *more than ninety-five categories of documents* from the ZHP Parties, which have resulted in more than 3.5 million pages of documents produced.
- The third *Aerospatiale* factor directs the Court to consider whether the information at issue originated in the United States or abroad, *not* whether the information has been disclosed, as argued by Plaintiffs. *See Dkt. 1273* at 10-11. Here, *it is absolutely uncontested that the information at issue originated in China*. *See Richmark*, 959 F.2d at 1475 (emphasizing that where the information originated bears on the analysis because the people that produced it "are subject to the law of that country in the ordinary course of business").
- As to whether Plaintiffs can obtain the information at issue by other means, the documents and communications at issue primarily involve ZHP's communications with Chinese regulatory authorities regarding the discovery of nitrosamines in valsartan and ZHP's subsequent investigation. *It is undisputed that the ZHP Parties have produced thousands of documents regarding the discovery of and investigation into the nitrosamine impurity—including real-time internal communications and testing data*, which are inherently more comprehensive than any summary report provided to Chinese regulators. Thus, Plaintiffs have presented no credible argument that they do not have an alternative means to obtain the responsive information contained in the withheld documents. To the extent Plaintiffs now claim that communications with the Chinese regulatory authorities could potentially demonstrate that ZHP "sought to influence foreign regulators" (*see Dkt. 1273* at 10-11) through the Chinese government, even if this allegation were proven to be true, it would have no bearing whatsoever on the ZHP Parties' potential liability for Plaintiffs' claims.

- With respect to the fifth *Aerospatiale* factor, the extent of a foreign nation’s interest in protecting its “secrets” is evidenced primarily by the scope of its protective laws, the strict enforcement of those laws, and the possibilities of severe sanctions and penalties (*see Reinsurance Co. of Am. v. Administratia Asigurarilor de Stat (Admin. of State Ins.)*, 902 F.2d 1275, 1280 (7th Cir. 1990)), **not** by a party’s unfounded speculation as to what a country’s national interests are. Further, to the extent Plaintiffs now seek to manufacture doubt about the declaration of Ms. Xueyu Yang because of her use of the word “may” to describe certain actions that the Chinese government could potentially take ([Dkt. 1273](#) at 1, 7, 12), Ms. Yang’s choice of words is wholly unsurprising given that she is not speaking on behalf of any Chinese government authority, but is instead basing her opinion off many years of experience practicing law in China.
- Plaintiffs have failed to present any evidence to rebut Ms. Yang’s declaration, as well as the statutes cited therein, which demonstrate that the ZHP Parties will face hardship in the form of potential civil and criminal penalties if the documents at issue are ordered to be produced. Although Plaintiffs cite *Autodesk, Inc. v. ZWCAD Software Co.*, No. 5:14-cv-01409-EJD, 2015 WL 1928184 (N.D. Cal. Mar. 27, 2015) in an attempt to argue that the ZHP Parties will not face hardship, *Autodesk* does not support that proposition. Rather, unlike this case, the plaintiff in *Autodesk* supported its motion to compel with expert testimony on Chinese law, and the defendant from whom the documents were sought did not proffer any expert to substantiate its claim of hardship. *Id.* at \*4. Here, unlike the defendant in *Autodesk*, the ZHP Parties have presented unrebutted evidence through the declaration of Ms. Yang of the criminal and civil penalties that could be imposed upon them if the documents at issue were produced.
- Finally, defying all logic, Plaintiffs now argue that the ZHP Parties’ good faith effort to reduce the number of documents withheld on the basis of Chinese state secrecy laws is somehow indicative of bad faith. However, the ZHP Parties have consistently acted in accordance with the process established by Judge Schneider for producing logs and reviewing Plaintiffs’ challenges, and this Court has noted it was “favorably impressed by the level of review that the documents went through . . . ***it shows that [the ZHP Parties are] really operating in good faith here*** and I did want to note that.” *See* 3-16-21 Hrg. Tr. at 38:17-18 (emphasis added).

### III. CONCLUSION

For the reasons set forth herein, this Court should strike Plaintiffs' arguments related to the *Aerospatiale* and *Richmark* factors from their reply brief, or grant the ZHP Parties leave to file a sur-reply brief to address those new arguments, and deem this brief the ZHP Parties' sur-reply.

June 1, 2021

Respectfully submitted,

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